

Message Text

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ORIGIN HEW-06

INFO OCT-01 EUR-12 EA-12 ISO-00 OES-09 SIG-03 EB-08
COME-00 L-03 MED-05 CIAE-00 INR-10 NSAE-00 /069 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: DKING
DHEW/PHS/OASH/OIH: RFISCHER
EUR/CE:SKLINGAMAN ;EUR/WE:VBROD
EUR/NE:HWOOLFLEY
EUR/SE:JMORTON ;EA/TIMBS:DFIELD
EA/K:UPO,T-,
EUR/NE:RWOODS
EUR/NE:RGREY
EUR/WE:KSMITH

-----078876 222343Z /23

P 222156Z AUG 78
FM SECSTATE WASHDC
TO AMEMBASSY BONN PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY ATHENS PRIORITY
AMEMBASSY SEOUL PRIORITY
AMEMBASSY STOCKHOLM PRIORITY
AMEMBASSY COPENHAGEN PRIORITY
AMEMBASSY MADRID PRIORITY
AMEMBASSY ROME PRIORITY
AMEMBASSY KUALA LUMPUR PRIORITY

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E.O. 11652: N/A

TAGS: OGEN ETRD, EIND, SWEL, TBIO, GW, UK, GR, KS, SW,

SUBJECT: FDA ADVISORY - FIRM INITIATED RECALL OF ANTI-RH
TYPING SERUM (RECALL B-0I0-8)

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1. FDA ADVISES OF THE FOLLOWING FIRM INITIATED RECALL:
PRODUCT INVOLVED - THE PRODUCT IS ANTI-RH TYPING SERUM ANTI-
RHO (ANTI-DO) (HUMAN) FOR SLIDE AND RAPID TUBE TEST. THE
PRODUCT IS PACKAGED IN 5 ML, 100 ML, AND 100 ML BOTTLES.

2. PRODUCT IDENTIFICATION: THE PRODUCTS ARE PACKAGED IN
GLASS BOTTLES WITH PAPER LABELS WHICH READ IN PART AS

FOLLOWS (BY BOTTLE SIZE):

3. 5ML SIZE: "S-300 5 ML S 300-L-4 ANTI-RH TYPING SERUM, ANTI-RHO (ANTI-D) (HUMAN) SLIDE AND RAPID TUBE TEST. U.S. LICENSE 344 PRESERVATIVE: SODIUM AZIDE - 1:1,000 MEETS FDA POTENCY REQUIREMENTS, SPECTRA TM BIOLOGICALS DIV. OF BECTON, DICKINSON AND CO....OXNARD, CA 93030.

4. 10 ML SIZE: SAME AS 5 ML BOTTLES EXCEPT "S-301 10 ML S 300-L-4.....

5. BULK 1000 ML BOTTLE: "EX300-L-3 ANTI-D BLOOD GROUPING SERUM FOR SLIDE AND RAPID TUBE TEST 1000 ML VIALS.... PRESERVATIVE SODIUM AZIDE, DO NOT USE IF TURBID, STORE BETWEEN 2 AND 8 DEGREES CENTIGRADE...CAUTION: FOR MANUFACTURING, PROCESSING, OR REPACKAGING....FOR EXPORT ONLY....U.S. LICENSE NO. 344....MANUFACTURED BY:....."

6. THE 5 AND 10 ML SIZES COME IN A SMALL CARTON WITH SEE THRU CELLO WINDOW. THE CARTON READS IN PART: "SPECTRA BIOLOGICALS IN VITRO DIAGNOSTIC REAGENT SEE INSERT FOR DIRECTIONS...." THE LOT NUMBERS BEING RECALLED ARE D-94 D-195, D-196, D-197, D-198, D-199, AND D-200.

7. REASON FOR RECALL: THE PRODUCT MAY CAUSE POSITIVE RESULTS WHEN USED FOR PERFORMING D U TEST WHICH IS CAUSED UNCLASSIFIED

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BY THE PRESENCE OF ANTI-WRA ANTIBODY.

8. THIS WAS DISCOVERED BY THE FIRM FOLLOWING UP A CONSUMER COMPLAINT WHERE THE COMPLAINANT REPORTED THE FOLLOWING: A POSITIVE D U TEST (1 PLUS AGGLUTINATION) HAD BEEN NOTED IN TESTING A DONOR, PREVIOUSLY TYPED AS D AND U NEGATIVE. LOT D-195 WAS USED. A DIRECT ANTIGLOBULIN TEST ON THE DONOR'S RED CELLS WAS NEGATIVE. THE CAUSE OF THE POSITIVE D U TEST WAS UNEXPLAINED.

9. THE FIRM BEGAN LABORATORY TESTING AS A RESULT OF THE CONSUMER COMPLAINT WHICH REVEALED THE PRESENCE OF A REACTING ANTI-WRA ANTIBODY IN SEVERAL LOTS OF SPECTRA ANTI-RHO (ANTI-D) TYPING SERUM FOR SLIDE AND RAPID TUBE TEST. AN ANTI-WRA ANTIBODY WAS DEMONSTRATED IN LOT NUMBERS D-194, D-195, D-196, D-197, D-198, D-199, D-200. THE ANTI-WRA ANTIBODY MAY REACT WITH RHO NEGATIVE RED CELLS THAT ARE POSITIVE FOR THE LOW FREQUENCY ANTIGEN WRA. THE FIRMS LABORATORY FINDINGS ARE THAT THE REACTIONS WITH RHO (D) NEGATIVE WRA POSITIVE RED CELLS WERE 1 PLUS OR LESS IN AGGLUTINATION STRENGTH.

10. THE FIRM'S ANALYSES INCLUDED REPEAT ANALYSIS ON VARIOUS ANTI-D LOTS AND COMMON RA-POOL. RAW POOLS D77-4(F), D78-1(F), D78-2(F), AND D78-3(F) CONTAINED THE ANIT-WRA ANTIBODY. THE FIRM SENT MAILGRAMS TO ALL CONSIGNEES ON 6-12-78. THIS WAS FOLLOWED BY LETTERS ON 6-14-78. THE LETTERS INCLUDED POSTCARDS FOR RETURN TO THE FIRM AS ACKNOWLEDGEMENT OF THE RECEIPT OF NOTIFICATION. THE CONSIGNEES WERE PROVIDED WITH ALERT STICKERS FOR BOTTLES OF THE PRODUCT AND REVISED INSTRUCTIONS FOR USE WITH THE PRODUCT.

11. MANUFACTURER/RECALLING FIRM: SPECTRA TM BIOLOGICALS, DIVISION BECTON, DICKINSON AND CO., 2)01 E. GONZALES RD., OXNARD, CALIFORNIA 93030.
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12. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE BEEN ADVISED OF RECALL AND NECESSARY ACTION. CONSIGNEE QUESTIONS REGARDING RECALL PROCEDURES SHOULD BE REFERRED TO U.S. FIRM.

13. FOREIGN CONSIGNEES AS PROVIDED TO FDA BY FIRM ARE AS FOLLOWS:

A. JOHNSON AND CO., GMBH, WESTRASSE 36, 401 HILDEN, GERMANY, ATTN: BLOOD BANK

BECTON DICKINSON, ATTN: BLOOD BANK SUPERVISOR, YORK HOUSE - EMPIRE WAY, MIDDLESEX, ENGLAND

P.T. GEROLYMATOS, ATTN: BLOOD BANK SUPERVISOR, 63 RUE SOCRATOUS, ATHENS, GREECE

DAI-ICHI KANGYO BANK LTD., SEOUL AIRPORT, IMP. DEC. M70I804 NS0085, SEOUL KOREA, FOR LOTTE SANGSA CO., LTD, SEOUL, KOREA

A. JOHNSON AND CO., H.A.B., C/O BALLENIUS AND LEFFLER A.B. BULLTAFTA AIRPORT, MALMO, SWEDEN, ATTN: BLOOD BANK SUPERVISOR

A JOHNSON COPENHAGEN DENMARK, C/O J.A. JORGENSON AND SON, ATTN: BLOOD BANK SUPERVISOR, 3 FREDRICKSVEJ DK. 2000, COPENHAGEN F. DENMARK

PRONADISA, ATTN: BLOOD BANK SUPERVISOR, PEDRO DE VALDIVIA 36, MADRID 6, SPAIN

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HAIMA PLASMADERIVALI SPA, ATTEN: BLOOD BANK SUPERVISOR,
RAMP 2 L. DAVINCI AIRPORT, ROME, ITALY

GETZ CORP: (M) SDN BHD LOT 18A, RD., 223, ATTEN: SHEAH
YENG SANG, PETALIN JAYASELONGON, MALAYSIA. CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: BLOOD
Control Number: n/a
Copy: SINGLE
Draft Date: 22 aug 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE213293
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Document Unique ID: 00
Drafter: JRWEINROTH, MD:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780343-1035
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780836/aaaabduw.tel
Line Count: 180
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 4162635f-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
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Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1656533
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - FIRM INITIATED RECALL OF ANTI-RH TYPING SERUM (RECALL B-010-8) UNCLASSIFIED
TAGS: OGEN, ETRD, EIND, SWEL, TBIO, GE, UK, GR, KS, SW
To: BONN LONDON MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/4162635f-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014